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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,897	07/30/2003	Itaru Sakou	1448.1042	6247
21171 7590 05/27/2009 STAAS & HALSEY LLP SUITE 700 1201 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER				
LIN, JERRY				
ART UNIT		PAPER NUMBER		
1631				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/629,897

**Applicant(s)**

SAKOU, ITARU

**Examiner**

JERRY LIN

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 25, 26, 28, 29 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 26, 28, 29, 35 and 36 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 31-34 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants' arguments and amendments, filed February 20, 2009, have been fully considered and they are deemed to be persuasive in-part. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Status of the Claims***

Claims 1, 2, 25, 26, 28, 29, and 31-40 are under examination.

### ***Claim Rejections - 35 USC § 112, 1st Paragraph***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 33 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement in light of Cohen et al. (Nature Genetics, October 2000, Volume 26, pages 183-186). The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546

(BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

(1) the quantity of experimentation necessary – Because it is unclear how sensitivity and specificity relate to distance, further experimentation is needed.

(2) the amount of direction presented – The specification does not teach how to derive a distance from the ratios that define sensitivity or specificity.

(3) the presence or absence of working examples – Although the specification does provide examples, the examples do not include teachings of how to derive a distance from the ratios that define sensitivity or specificity.

(4) the nature of the invention – The invention is drawn to predicting a gene expression site by calculating a distance between a unknown gene and known genes and comparing that distance to a predetermined distance based on sensitivity and specificity.

(5) the state of the prior art – The prior art does not teach defining an upper limit of distance based on sensitivity and specificity.

(6) the relative skill of those in the art – The level of skill of those in the art is high.

(7) the predictability or unpredictability of the art – Without knowledge of how to derive distance from sensitivity and specificity, the art is unpredictable.

(8) the breadth of the claims – The claims are drawn to particular computational method of predicting a gene expression site.

Applicants have also amended the claims to include a predetermined distance relation or threshold based sensitivity and specificity that define an upper limit of the distance. According to page 17 of the specification, sensitivity is defined as  $A/(A+B)$  where A is the number of expression sites of a unknown gene determined by another method that have been predicted and B is the number of expression sites of a unknown gene determined another method that have been not been predicted. Specificity is defined as  $b/(a+b)$  where a is the number of non-expression sites of a unknown gene determined another method that have been predicted and B is the number of non-expression sites of a unknown gene determined another method that have been not been predicted. However, the ratio that defines specificity and sensitivity do not appear to have a term in the equation that relates to distance. Thus, it is unclear how one of skill in the art is to define the upper limit of the distance using specificity and sensitivity. One of skill in the art would not know how to determine distance from these equations. Without further guidance from the specification or method steps, one of skill in the art would not be enabled to use the invention as claimed to support a user to predict expression sites without undue experimentation.

Response to Arguments

4. Applicants have responded to this rejection by amending the previously presented independent claims and removing the terms "specificity" and "sensitivity". While the rejection has been withdrawn for these claims, these terms still appear in claim 33 and new claims 37-40. Thus the rejection is applied to these terms. Applicants also stated that the terms do not appear in claim 33. However, the last line

of claim 33 recites, "the distance based on the sensitivity and the specificity which define an upper limit of the distance."

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 33 and 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps required to determine a predetermined distance relation using sensitivity and specificity. Sensitivity is defined as a ratio of expression sites predicted to expression sites previously determined that it is where the unknown gene expression by another method (specification, page 16). Specificity is defined as the ratio of expression sites not predicted to expression sites previously determined that it where the unknown gene never expresses by another method (specification, page 16). It is unclear what further steps are required to derive a distance from the ratios that define sensitivity and specificity.

**Response to Arguments**

7. Applicants have responded to this rejection by amending the previously presented independent claims and removing the terms "specificity" and "sensitivity". While the rejection has been withdrawn for these claims, these terms still appear in claim 33 and new claims 37-40. Thus the rejection is applied to these terms.

Applicants also stated that the terms do not appear in claim 33. However, the last line of claim 33 recites, "the distance based on the sensitivity and the specificity which define an upper limit of the distance."

### ***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 31-34, and 37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a method of predicting a gene expression site. However, as the method does not recite a physical transformation of matter, the method must be tied to a machine to be patentable subject matter (For further explanation see, In Re Bilski (No. 2007-10030, decided 10/30/2008)). In the instant case, the claimed method steps are not tied to a machine, and thus are non-statutory.

### ***Allowable Subject Matter***

Claims 25, 26, 28, 29, 35, and 36 are allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/  
Examiner, Art Unit 1631  
5/24/09